



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,787	10/27/2000	Victor Levy	50824-2-2-1	6687

22504 7590 01/06/2005

DAVIS WRIGHT TREMAINE, LLP  
2600 CENTURY SQUARE  
1501 FOURTH AVENUE  
SEATTLE, WA 98101-1688

EXAMINER

PASS, NATALIE

ART UNIT PAPER NUMBER

3626

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/698,787

Applicant(s)

LEVY, VICTOR

Examiner

Natalie A. Pass

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-11 is/are rejected.
- 7) ☒ Claim(s) 1 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10 September 2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Notice to Applicant***

1. This communication is in response to the amendment filed 10 September 2004. Claim 1 has been amended. Claims 2-7 have been cancelled. Claims 8-11 have been newly added. Claims 1 and 8-11 remain pending. The IDS statement and Declaration from Applicant filed 10 September 2004 have been entered and considered.

***Response to Amendment***

2. The Declaration from Applicant under 37 CFR 1.132 filed 10 September 2004 is insufficient to overcome the rejection of claim 1 based upon the rejections over Haessler et al., U.S. Patent Number 4, 130, 881 in view of Iliff et al., U.S. Patent Number 6, 206, 829 under 35 U.S.C. 103(a) as set forth in the last Office action because:

It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

Furthermore, it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Additionally, Examiner observes that the list of publications on page 2 of the Declaration from Applicant, which are noted as being attached to the Declaration, have neither been found by

Art Unit: 3626

(nor provided to) the Examiner nor noted in a form PTO-1449 or Information Disclosure Statement.

*Specification*

3. The amendment filed 10 September 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. "New matter" constitutes any material which meets the following criteria:

a) It is added to the disclosure (either the specification, the claims, or the drawings) after the filing date of the application, and

b) It contains new information which is neither included nor implied in the original version of the disclosure. This includes the addition of physical properties, new uses, etc. The added material which is not supported by the original disclosure is as follows:

- "a matrix" as disclosed in claim 1, line 8.

In particular, Applicant does not point to, nor was the Examiner able to find, any support for this newly added language within the specification as originally filed on 27 October 2000. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

4. If Applicant continues to prosecute the application, revision of the specification and claims to present the application in proper form is required. While an application can be

Art Unit: 3626

amended to make it clearly understandable, no subject matter can be added that was not disclosed in the application as originally filed on 27 October 2000.

### *Claim Objections*

5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 1(c) has been renumbered to be claim 1(d) at line 19.

6. Claim 11 is objected to because of the following informalities: in the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered). See 37 CFR 1.121 (c). Claim 11 has no status identifier. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 3626

8. Newly amended claim 1, and newly added claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Independent claim 1 recites limitations that are new matter, as discussed above, and is therefore rejected.

(B) Claims 8-11 incorporate the features of independent claim 1, through dependency and are also rejected.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Newly amended claim 1 and newly added claims 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites "from the input variables" in section (c), however input variables are recited both in section (a) and in section (b). As such it is unclear whether the input variables referred to in section (c) are the input variables in section (a) or the input variables in section (b). There is lack of antecedent basis for this limitation in the claim. For the purpose of finding art, Examiner assumes the input variables referred to are those in section (a).

Art Unit: 3626

- Claim 1 recites "a matrix " in section (a). In view of the fact that the meaning of this term is not defined in the specification, for the purpose of applying art Examiner interprets this to mean a table.
  - Claim 8 recites "the outcome" in line 3 and "the post-examination calculation" in line 5. There is insufficient antecedent basis for these limitations in the claim.
  - Claim 10 recites "the accuracy" in line 2. There is insufficient antecedent basis for this limitation in the claim.
11. The rejection of claim 5 under 35 U.S.C. 112, second paragraph for being indefinite is hereby withdrawn due to the amendment filed 10 September 2004.

***Claim Rejections - 35 USC §101***

12. The rejection of claims 1-4 under 35 U.S.C. 101 for being drawn to non-statutory subject matter is hereby withdrawn due to the amendment filed 10 September 2004.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3626

14. Claims 1, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haessler et al., U.S. Patent Number 4, 130, 881 in view of Iliff et al., U.S. Patent Number 6, 206, 829 for substantially the same reasons given in the previous Office Action (paper number 6), and further in view of Khorasani et al., U.S. Patent Number 6, 029, 138. Further reasons appear below.

(A) Claim 1 has been amended to include the recitation of

- ♦ (a) "providing an automated database as a real-time web-based system that includes statistically accrued, evidence-based data that is input from multiple sources via a common web-based system template, the common web-based system template providing a medium for entering data into the database that includes actual diagnoses of patient symptoms from multiple patient populations at different locations, and further, the common template includes a matrix of a plurality of independent input variables coupled with a plurality of outcomes for each input variable, and still further, each outcome being evidence-based from prior diagnoses taken from patient populations" in lines 3-11;
- ♦ "patient symptoms and information as input variables" in lines 13-14;
- ♦ "using the statistically accrued evidence-based outcomes from the input variables to generate" in lines 15-16; and
- ♦ "for each diagnosis that is made immediately available to a user" in lines 19-20.

As per these new limitations, Haessler and Iliff teach a process further comprising

(a) providing an automated database as a real-time web-based system (Iliff; see at least Figure 25a, Figure 30, column 68, lines 30-60) that includes statistically accrued, evidence-based



Art Unit: 3626

data (Iliff; see at least Figure 27, Items 2284, 2300, column 12, lines 34-51, column 22, lines 60-65) that is input from multiple sources via a common web-based system template or html document or form, the common web-based system template providing a medium or form for entering data into the database that includes actual diagnoses of patient symptoms from multiple patient populations at different locations (Iliff; see at least Figure 29, Item 2408, column 4, line 45 to column 5, line 17, column 68, line 6 to column 69, line 32, column 70, lines 1-14, column 76, lines 55-59), and further, the common template includes a matrix or table of a plurality of independent input variables coupled with a plurality of outcomes for each input variable (Iliff; see at least Figure 6, Item 256, column 21, lines 30-37, column 56, line 40 to column 57, line 3), and still further, each outcome being evidence-based from prior diagnoses taken from patient populations (Iliff; see at least column 23, lines 45-53, column 44, line 33 to column 45, line 6, column 52, lines 27-33, column 72, lines 29-30);

(b) providing a plurality of patient symptoms and information as input variables (Haessler; see at least Figure 3, Figure 4, Figure 5, Figure 6, column 1, line 45 to column 2, line 39, column 3, line 29 to column 4, line 39, column 4, line 60 to column 5, line 6); and

(d) for each diagnosis that is made immediately available to a user (Iliff; see at least Figure 30, column 4, line 45 to column 5, line 17, column 68, line 61 to column 69, line 32, column 76, lines 55-59).

Although Haessler and Iliff teach

(c) the system presenting or generating a display of a plurality of disease categories or symptomatic areas that are related to the symptoms indicated in step b (Haessler; column 4, lines

Art Unit: 3626

14-39), Haessler and Iliff fail to explicitly disclose using the statistically accrued evidence-based outcomes from the input variables to generate the disease information or feedback.

However, the above features are well-known in the art, as evidenced by Khorasani.

In particular, Khorasani teaches

using the statistically accrued evidence-based outcomes from the input variables to generate the disease information or feedback (Khorasani; see at least Figure 1, Figure 6, Figure 7, column 2, line 57 to column 3, line 61, column 4, line 44 to column 6, line 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Haessler and Iliff to include using the statistically accrued evidence-based outcomes from the input variables to generate the disease information or feedback, as taught by Khorasani, with the motivation of altering physician behavior and improving patient outcomes by applying managed utilization of various diagnostic studies to reduce costs (Khorasani; column 4, lines 16-26).

The motivations for combining the respective teachings of Haessler and Iliff are as given in the rejection of claim 1 in the prior Office Action (paper number 6) and incorporated herein.

The remainder of claim 1 is rejected for the same reasons given in the prior Office Action (paper number 6, section 11, pages 6-7), and incorporated herein.

(B) As per newly added claims 8-11, Haessler, Iliff and Khorasani teach a process as analyzed and discussed in claim 1 above including

providing a ranked probability for multiple diagnoses from the multiple input variables by using an algorithm that generates or calculates at least one likelihood ratio for each

Art Unit: 3626

independent input variable, for estimating the probability of each diagnosis (Iliff; column 39, line 29 to column 40, line 67);

wherein the probability of each diagnosis is determined prior to conducting a patient examination for a particular disease and redetermined following the outcome of the patient examination, thereby incorporating relevant information in the form of a linked succession of likelihood ratios from the examination into the post-examination calculation (Iliff; column 39, line 24 to column 41, line 52);

including multiplying a chain of likelihood ratios to produce a product that refines the accuracy of ranked probabilities (Iliff; column 63, lines 34-51); and

including continuously updating and expanding the statistically accrued evidence-based data by using the common system template or entry module to add statistical information from patient populations from a plurality of input sources (Khorasani; see at least Figure 1, Figure 6, Figure 7, column 2, line 57 to column 3, line 61, column 4, line 44 to column 6, line 26), (Iliff; Figure 30, Items 2358, 2360, column 4, lines 10-13, column 12, lines 46-51, column 57, lines 13-15).

The motivations for combining the respective teachings of Haessler, Iliff and Khorasani are as given in the rejections of claim 1 above and in the prior Office Action (paper number 6) and incorporated herein.

### ***Response to Arguments***

15. Applicant's arguments filed 10 September 2004 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 10 September 2004.

(A) At the paragraph bridging pages 4-5 of the 10 September 2004 response Applicant discusses the declaration of the inventor. As per the "Declaration of Dr. Victor Levy" document, filed 10 September 2004, Applicant argues that affidavits and declarations containing evidence of secondary consideration such as long-felt but unsolved needs must be considered by the Examiner in determining the issue of obviousness.

In response, the Examiner recognizes that secondary considerations such as commercial success and long-felt but unsolved needs must be considered and does not dispute their relevance in determining the issue of obviousness. However, it is respectfully submitted that commercial success and long-felt need are secondary considerations that must be considered in light of the totality of all of the evidence present in the case (e.g., applicable prior art, knowledge of the ordinarily skilled artisan, etc.), and that non-obviousness can be established ONLY when the totality of the rebuttal evidence of non-obviousness (and not just the secondary considerations of non-obviousness such as commercial success and long-felt need) outweighs the evidence of obviousness. As such, the Examiner is concerned that, aside from merely arguing the secondary considerations of non-obviousness, Applicant does not point to any specific distinction(s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111(b) states, "A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the requirements of this section." Applicant has failed to specifically point out how the language of the claims patentably distinguishes them from the applied references. Also, arguments or conclusions of Attorney

Art Unit: 3626

cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In re Schulze*, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Mertizner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Applicant argues that the affidavit, submitted 10 September 2004, demonstrates a long-felt need for the "process for facilitating diagnosis of medical symptoms" (allegedly, Applicant's claimed invention) and that no adequate solution has existed for utilizing evidence-based analyses for generating medical diagnoses.

In response, the affidavit submitted 10 September 2004 is insufficient to meet the criteria set forth in MPEP § 716.04 for establishing long-felt need and failure of others because:

(i) The affidavit does not provide any evidence of the failure of others in solving the long-felt problem or of any unsuccessful attempts at meeting the long-felt need. *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 217 USPQ 1281 (Fed. Cir. 1983). Further, the failure to solve a long-felt need may be due to factors not addressed in the exhibits such as lack of interest or lack of appreciation of an invention's potential or marketability rather than want of technical know-how. *Scully Signal Co. v. Electronics Corp. of America*, 196 USPQ 657 (1st. Cir. 1977); and

(ii) The affidavit and response does not sufficiently show that the long-felt need must not have been satisfied by another before the invention by Applicant. *Newell Companies v. Kenney Mfg. Co.*, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). In fact, the teachings of the applied references, Haessler, Iliff and Khorasani, clearly demonstrate a solution to the long-felt need presented in the affidavit and purported by Applicant, as their collective teachings are directed to a process for facilitating diagnosis of medical symptoms, having each element presently claimed.

Art Unit: 3626

Moreover, what is construed by the Applicant as evidence of a long-felt need is respectfully submitted by Examiner to be further motivation that existed in the art prior to Applicant's invention for turning to the teachings of Haessler, Iliff and Khorasani for solutions.

As per the submitted affidavit, it is respectfully submitted that the affidavit of Victor Levy is insufficient to overcome the grounds of rejection given in the previous Office Actions because it appears to be self-serving in that the affidavit merely provides statements made by the named inventor. As such, the Examiner is not sure how much weight can be attributed to such statements, as they are neither positively and definitely confirmed or corroborated by the other third parties/objective affiant(s) who have also filed affidavits, for the reasons set forth above, and because no other forms of hard evidence (i.e., graphs, charts, sample survey forms, official survey results) have been provided to evidence the averred statements.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness.

(B) At pages 11-16 of the 10 September 2004 response Applicant argues that the features in the Application are not taught or suggested by the applied references. In response, all of the limitations which Applicant disputes as missing in the applied references, including the newly added limitations of the amendment filed 10 September 2004, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the combined teachings of Haessler, Iliff and Khorasani, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number

Art Unit: 3626

6), and incorporated herein. In particular, Examiner notes that the recited features of "providing an automated database as a real-time web-based system that includes statistically accrued, evidence-based data" and the "common template includes a matrix or table of a plurality of independent input variables coupled with a plurality of outcomes for each input variable" and "reporting a series of possible diagnoses and probabilities for each diagnosis" are taught by the combination of applied references (Iliff; see at least Figure 6, Item 256, Figure 27, Items 2284, 2300, Figure 30, column 12, lines 34-51, column 21, lines 30-37, column 22, lines 60-65, column 39, line 29 to column 40, line 67, column 41, lines 39-52, column 56, line 40 to column 57, line 15, column 68, lines 30-60), (Haessler; see at least Figure 3, Figure 4, Figure 5, Figure 6, column 1, line 45 to column 2, line 39, column 3, line 29 to column 4, line 39, column 4, line 60 to column 5, line 6), (Khorasani; see at least Figure 1, Figure 6, Figure 7, column 2, line 57 to column 3, line 61, column 4, line 44 to column 6, line 16). Please note that Examiner interprets Iliff's "[b]ased upon the answers to the diagnostic screening questions, the MDATA system 100 reorders the first list. The first list then becomes a list of the possible causes of headache in decreasing levels of probability in the patient seeking consultation ... [i]f the MDATA system 100 concludes that migraine is the most likely cause of the patient's headache, then migraine will now be ranked at the top of the first list (Iliff; column 39, line 65 to column 40, line 5), and Iliff's "treatment table that can be updated instantaneously to provide the most current treatment recommendations" (Iliff; column 57, lines 13-15)," and Iliff's "[t]he MDATA system 100 stores the scores of all the screening and confirmation questions in what are called "session memory variables" ... [...]... in the symbol table [reads on "matrix"]. It is, in part, these scores that are then used to determine the probability of one diagnosis versus another," (Iliff; column 40, lines

Art Unit: 3626

59-63) as reading on " statistically accrued, evidence-based data" and on evidence-based systems for diagnosing diseases.

With regard to Applicant's argument at paragraph 2 on page 12 of the 10 September 2004 response that the applied art fails to disclose a matrix or table of a plurality of independent input variables coupled with a plurality of outcomes, Examiner respectfully disagrees. Examiner interprets Iliff's "Treatment Table" process that utilizes a "'look-up' table" [reads on matrix] using a plurality of independent input variables or diagnoses coupled with a plurality of outcomes or treatments as reading on Applicant's limitations. In addition, Khorasani teaches the use of a common system template or structured order entry module to accumulate statistically accrued, evidence-based data to generate the disease information or feedback (Khorasani; see at least Figure 1, Figure 3, Figure 5, Figure 6, Figure 7, column 2, line 57 to column 3, line 61, column 4, line 44 to column 6, line 16). In addition, Examiner interprets Khorasani's "[i]n the present invention, decision support is evidence-based, i.e., specified indications for a selected study are compared to actual results for previous studies having the same indications, to determine the likelihood that significant results will be obtained from the study," as reading on "statistically accrued, evidence-based data" and Iliff's "[b]ased upon the answers to the diagnostic screening questions, the MDATA system 100 reorders the first list. The first list then becomes a list of the possible causes of headache in decreasing levels of probability in the patient seeking consultation ... [...]... [i]f the MDATA system 100 concludes that migraine is the most likely cause of the patient's headache, then migraine will now be ranked at the top of the first list" (Iliff; column 39, line 65 to column 40, line 5) as reading on reporting "probabilities for each diagnosis."



With regard to Applicant's argument at paragraph 3 on page 12 of the 10 September 2004 response that the applied art fails to disclose the limitations in newly added claim 8 of "providing a ranked probability... by using an algorithm that generates or calculates at least one likelihood ratio for each independent input variable," Examiner respectfully disagrees. Examiner interprets "the MDATA system's paradigm is fundamentally an algorithmic one" and "the system establishes the most likely cause of the patient's headache" and "[t]he first list is a ranking of the most common causes of headache ... " and "[b]ased upon the answers to the diagnostic screening questions, the MDATA system 100 reorders the first list. The first list then becomes a list of the possible causes of headache in decreasing levels of probability" (Iloff; column 39, line 24 to column 40, line 67) as reading on these limitations.

With regard to Applicant's argument at paragraph 4 on page 12 of the 10 September 2004 response that the applied art fails to disclose the limitations in newly added claim 9 of "wherein the probability of each diagnosis is determined prior to conducting a patient examination for a particular disease and redetermined following the outcome of the patient examination" Examiner respectfully disagrees. Examiner interprets Iliff's "[a]fter obtaining the answers to the migraine screening questions, if the probability that the patient is suffering from a migraine headache does not reach an established threshold, the next cause of headache on the reordered first list is considered and pursued as a diagnosis" and "[f]rom the answers to the migraine confirmation questions, the MDATA system 100 calculates the probability of confirmation of migraine" and "If the probability of migraine headaches reaches threshold, but the probability of confirmation

Art Unit: 3626

of migraine does not reach threshold, then, as mentioned, the system pursues the next diagnostic cause of headache" (Iliff; column 39, line 24 to column 41, line 52) as reading on these limitations.

With regard to Applicant's argument at paragraph 1 on page 13 of the 10 September 2004 response that the applied art fails to disclose the limitations in newly added claim 11 of "continuously updating and expanding the statistically accrued evidence-based data" Examiner respectfully disagrees. Examiner interprets Khorasani's "[i]n the present invention, decision support is evidence-based, i.e., specified indications for a selected study are compared to actual results for previous studies having the same indications, to determine the likelihood that significant results will be obtained from the study. Where available, data from existing scientific literature also may be used to enhance the online decision support" and "[b]y continued use of the present system, the result codes database will grow in the amount of information available and the appropriateness of various studies with respect to actual patient outcomes will become more apparent" (Khorasani; see at least Figure 1, Figure 6, Figure 7, column 2, line 57 to column 3, line 61, column 4, line 44 to column 6, line 26) and Iliff's "[p]rior medical advice systems suffer from the inability to be nearly instantly up-dated as new medical information is made available. The MDATA system regularly and frequently updates the treatment aspect of the system" and "[b]y applying the statistical information that is generated, the MDATA system not only provides the patient with advice that is continually improving, but it will also be able to pass along these probabilities to the entire medical community" and Iliff's "[t]he MDATA system 100 maintains a treatment table that can be updated instantaneously to provide the most current

Art Unit: 3626

treatment recommendations" (Iliff; Figure 30, Items 2358, 2360, column 4, lines 10-13, column 12, lines 46-51, column 57, lines 13-15) as reading on these limitations.

As to Applicant's note on page 13, Examiner thanks Applicant for correcting the technicality of the rejection of now cancelled claim 5.

### *Conclusion*

16. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references McCartney, U.S. Patent Number 5, 778, 345, Mcleod, U.S. Patent Number 6, 053, 866, Bond et al., U.S. Patent Number 6, 177, 940, Gray, U.S. Patent Number 6, 149, 585 and McIlroy et al U.S. Patent Number 5, 583, 758 teach the environment of utilizing past knowledge for diagnosis of medical symptoms.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

Art Unit: 3626

action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any response to this action should be mailed to:

**Commissioner of Patents and Trademarks**

**Washington D.C. 20231**

or faxed to: **(703) 305-7687.**

For informal or draft communications, please  
label "PROPOSED" or "DRAFT" on the front page of  
the communication and do NOT sign the  
communication.

After Final communications should be labeled  
"Box AF."

Hand-delivered responses should be brought to Crystal  
Park 5, 2451 Crystal Drive, Arlington, VA, Seventh Floor  
(Receptionist).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (703) 305-3980. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

Art Unit: 3626


20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (703) 305-9588. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 308-1113.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Natalie A. Pass

December 23, 2004



JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600